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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	A33477 PCT U	5826

7590 05/21/2002

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/21/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/673,872	WAI-CHIU SO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Sharmila S. Gollamudi	1616

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 20 February 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
  - a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____                                     |

## **DETAILED ACTION**

Amendment A, paper no., 10 is acknowledged.

Claims 1-24 are included in the prosecution of this application.

### ***Response to Arguments***

Applicant argues that Yu et al does not anticipate instant invention. The applicant argues that Yu does not suggest the instant composition. In regards to the 103(a) rejection, the applicant argues that Uchikawa teaches a hair tonic containing amine oxides and the combination would not overcome the instant amount of propylene glycol.

Applicant's arguments have been fully considered. The applicant is correct in that Yu et al do not clearly anticipate the instant invention. Although Yu et al does provide a specific example, Yu et al suggest the instant invention. Yu et al teaches the active agent in the range of .01-40% on column 6, lines 51-53. Further, Yu teaches the volume ratio of ethanol: water: propylene glycol to be 40:40:20 on column 7, lines 1-3. Therefore, the examiner's position is that Yu et al suggest the instant invention and the mere optimization of the amount of actives is within the skill of a practitioner in the art.

In regards to the arguments of Uchikawa, Uchikawa suggests the use of minoxidil as an additional active agent, note column 4, lines 7-33). The instant claim language does not exclude the use of other actives, i.e. amine oxides, in the composition. Further, Uchikawa is relied upon for it's teaching of obtaining similar results using ethanol or benzyl alcohol.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al (5571841) by itself or in combination with Kasting et al (5041439) or vice-versa.**

Yu et al teaches a therapeutic composition for hair loss that contains minoxidil (2%), water, ethanol, propylene glycol (16%), and lactic acid (Note example 3). Yu et al teaches the active agent in the range of .01-40% (col.6, lines 51-53). Further, Yu teaches the volume ratio of ethanol: water: propylene glycol to be 40:40:20 (col. 7, lines1-3). The composition is applied to the scalp to treat hair loss (Note example 3).

Yu et al does not provide an example with instant amount of minoxidil.

Kasting et al teaches a minoxidil acid salt made from an acid such as acetic or lactic acid (col. 6, lines 44-53). Kasting teaches using 12% active, 54% 1,2,6-hexanetriol, oleyl alcohol, and 30% ethanol (Note composition XIV). The reference teaches several ranges in the examples. Kasting teaches the amount of active also depends on factors such as the severity of the condition, the cause of the condition, the specific active used, etc. (col.7, lines 5-15).

Although, Yu does not provide a specific example, it is deemed obvious to one of ordinary skill in the art, in the absence of showing unexpected results, to manipulate the conditions to obtain the best possible results since Yu et al provides the general

guidance of the hair treating composition. One would be motivated to change the concentration of minoxidil depending on the severity of the condition. Further, Kasting et al teaches a hair loss composition and manipulating the solvent system and active agent to obtain a therapeutic composition without irritation.

**Claims 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al (5571841) by itself or in combination with Kasting et al (5041439) or vice-versa, in further view of Uchikawa et al (5156836).**

As set forth above, Yu and Kasting teach a hair loss composition containing a piperidinopyrimidine derivative and a solvent system.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol and benzyl alcohol. Further, the reference teaches a formulation where the alcohol-water mixture is in the instant ratio. (col. 3 and 4, line 45 through line 34). Uchikawa et al teaches the application of the hair composition for the treatment of hair loss.

It would have been obvious at the time the invention was made to use benzyl alcohol or ethanol in the solvent system since Uchikawa et al teaches the use of either alcohols in the hair tonic.

### ***Conclusion***

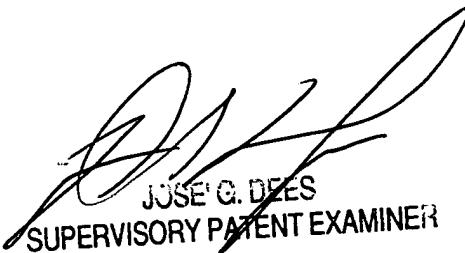
Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

  
May 9, 2002

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

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